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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,682	04/27/2001	Rolf Bjerkvig	1702.401900	8676

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Patent Administrator
FMC Corporation
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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/763,682	BJERKVIG, ROLF	
	Examiner	Art Unit	
	J. Eric Angell	1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *12,14-21,24-28,30 and 32*.

   Claim(s) withdrawn from consideration: _____.

8. ☒ The drawing correction filed on *26 February 2001* is a)☒ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: Applicants assert that the Offce Action fails to identify any credible evidence of a motivation, teaching, or suggestion that would have led persons of ordinary skill in the art who did not have the benefit of the hind sight provided by Applicant's disclosure to combine the teachings of the Aebischer application with those of the O'Reilly patent and the Skjak-Braek patent. Applicants argue that although the Office Action asserts that concerns over immunostimulation would have motivated those of ordinary skill in the art to encapsulate the producer cells alleged to be disclosed in the Aebischer application with the alginate disclosed in the Skjak-Braek patent, rather than the encapsulation devices disclosed in the Aebischer application, those of ordinary skill would not have been so motivated. Applicants contend that there is no reason to believe that those of ordinary skill having the Aebischer application before them would have been concemed with the immunostimulatory effect engendered by the encapsulated cells that the application discloses, much less sufficiently concerned to modify the application's disclosure in a way that would have produced any claimed inventions. Applicants conlcude that since the Aebischer application describes encapsulation of cells using means that prevent or reduce an immune response against the cells following implantation, those of ordinary skill in the art would not have been motivated by such concerns to modify its teachings. For these reasons, Applicants respectfully request withdrawal of the rejection.

In response, Applicants arguments have been fully considered, but are not persuasive for the following reasons. With respect to Applicants argument that the exnminer's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). With respect to Applicants argument that Aebischer describes encapsulation of cells using means that prevent or reduce an immune response against the cells following implantation, therefore, those of ordinary skill in the art would not have been motivated by such concerns to modify its teachings, it is respectfully pointed out, as indicated in the previous Office Action, that Aebischer teaches a composition (as well as methods of making and using said composition) comprising a cell that produces an antitumor protein (specifically, FasL) wherein the cell is encapsulated in an immunoisolatory device. Furthermore, Aebisher indicates that the encapsulating device can be produced from alginate (p. 15, lines 29-30). Aebischer does not indicate the exact composition of the encapsulating alginate. However, Skjak-Braek also teaches an encapsulated cell (such as a monocyte that produces TNF-alpha or IL-1, see column 8) wherein the encapsulated cell can be tansplanted into a subject to act as a drug or biological material delivery system. Furthermore, as previously indicated, Skjak-Braek specifically indicates the composition (i.e., the percent G, percent M) of the encapsulating alginate, and further teaches that an alignate with a high concentration of G and a low concentration of M has a reduced immunostimulatory effect when transplanted into a mammal. Therefore, Skjak-Braek clearly provides motivation for making the encapsulated cell wherein the encapsulating agent has a high G and low M concentration. Furthermore, considering that Aebischer and Skjak-Braek both teach thereapeutic compositions comprising encapsulated cells wherein the encapsulating material is an alginate that functions to protect the encapsulated cell from immune attack, it would have been obvious to one of ordinary skill in the art to substitute the encapsulating alginate of Skjak-Braek for the encapsulating alginate of Aebischer as the encapsulating alginates of Aebischer and Skjak-Braek were equivalents known for the same purpose (encapsulating cells for protection from immune response) (See MPEP 2144.06). It is respectfully pointed out that an express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious (In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)). For these reasons, Applicants arguments are not persuasive and the rejections are not withdrawn.

DAVE T. NGUYEN
PRIMARY EXAMINER